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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/757,344	01/09/2001	Pierre Jean Francois Layrolle	04148-00005	8849

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT	PAPER NUMBER
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1762

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DATE MAILED: 06/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/757,344

Applicant(s)

LAYROLLE ET AL.

Examiner

Jennifer Kolb Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claim Objections

1. The objection to claim 37 is withdrawn.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The rejection of claims 27, 28, and 33 under 35 U.S.C. 102(b) as being anticipated by Kokubo et al '122 has been withdrawn.
3. The rejection of claims 27-28 and 32 under 35 U.S.C. 102(e) as being anticipated by Li has been withdrawn in favor of the new 103 rejection over Li below.
4. Claims 27-33 and 36-43 are rejected under 35 U.S.C. 102(e) as being anticipated by Leitao.

Examiner maintains the rejection of claims 27-33 and 36-38.

In regard to the newly added limitation to claims 27 and 36 requiring the bond strength to be 40-65 Mpa, Examiner notes that Leitao does not teach a bond strength.

However, it is Examiner's position that such a property is inherent in the device of Leitao. Leitao teaches a coated implant with a coating, wherein the coating comprises a deposit of crystals nucleated directly on the implant from solution wherein said coating

comprises magnesium, calcium, and phosphate ions and induces formation of bone cells. Because the same chemicals are nucleated onto the same pre-treated surfaces, the bond strength between the implants and coatings of Leitao and Applicant will inherently be the same. If Leitao's bond differs from that of Applicant's it must be due to some limitation not present in Applicant's claims.

In response to newly added claims 39-43, Examiner notes the deposition of octacalcium phosphate (OCP) (table 2).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. Claims 34-35 and 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leitao.

Examiner maintains the rejection of claims 34-35.

In response to newly added claims 44-45, Examiner rejects these claims for the same reasons as were applied to claims 34-35.

In light of amendments, the following new 103 rejections are made:

6. Claims 27-28 and 32-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li.

Li teaches that which is disclosed in the previous office action. Additionally, Li teaches that the adhesion strength of the coating to a polished substrates is believed to be in

excess of 30MPa (col. 6, line 45). The range "in excess of 30 MPa" overlaps the range claimed by Applicant. Overlapping ranges are *prima facie* evidence of obviousness. It would have been obvious to one having ordinary skill in the art to have selected the portion of Li's range that corresponds to the claimed range. *In re Malagari*, 184 USPQ 549 (CCPA 1974).

Li teaches the use of carbonated calcium phosphate (claim 1).

Li teaches a coating thickness of 0.005 to 50 microns (claim 2), overlapping the range claimed by Applicant.

In regard to claim 36 requiring a second coating comprising calcium and phosphate ions over a first coating comprising calcium, phosphate, and magnesium ions, Examiner notes that the second coating is inclusive of an additional layer of the first coating. In this case, claim 36 differs from Li only in requiring two layers containing calcium and phosphate while Li only teaches one layer. It is well-settled that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. *In re Harza*, 124 USPQ 378 (CCPA 1960).

Additionally, depending on the thickness selected by Li, one layer containing calcium, phosphate, and magnesium would be indistinguishable from two, thinner layers of the identical chemicals.

7. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nonami.

Art Unit: 1762

Nonami teaches an implant substrate comprising calcium, phosphate, and magnesium ions joined with a coating material of the same make-up. (col. 4, lines 34 and 44). The bond strength between the two materials is 30-1000 MPa, overlapping the range set forth by Applicant (col. 13, line 13). Overlapping ranges are obvious for those reasons outlined above.

The materials of Nonami promote the formation of bones (col. 4, line 51).

Examiner recognizes that Nonami does not teach solution coating, however the Examiner provided a rationale above tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process. The burden shifts to Applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

Response to Arguments

8. Applicant's arguments filed 4/8/2002 have been fully considered but they are not persuasive.

Applicant argues Li does not teach alteration of pH, temperature, or concentration.

Examiner notes that such limitations are not present in Applicant's claims.

Applicant argues that Li does not have any supporting experimental data to prove that the adhesive bond strength is greater than 30 MPa and that, therefore, such a bond strength is merely speculation.

Examiner must take the teachings of Li at face value. Since Li teaches a bond strength of greater than 30 MPa, Examiner is not permitted to interpret the reference in a manner that is contradictory to that teaching.

Applicant argues that Leitao does not teach a bond strength.

It is Examiner's position that the bond strength of Leitao is inherently within the range claimed by Applicant, for those reasons outlined above.

Applicant argues that Leitao does not teach direct nucleation of the octacalcium phosphate onto the substrate.

Examiner notes that the octacalcium phosphate is an example of a calcium phosphate precipitate for use directly onto the substrate of Leitao.

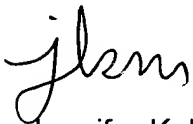
Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

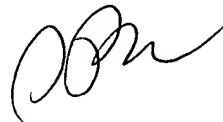
Art Unit: 1762

10. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3599 for regular communications and 703-305-3599 for After Final communications.

11. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
June 2, 2002



SHRIVE P. BECK
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